

RESPONSE

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-18, 28 - 30, and 37, as well as newly added claims 38 to 44, the only claims pending and currently under examination in this application.

Formal Matters

Claims 1-30 and 37-44 are pending after entry of the amendments set forth herein, of which claims 19 – 27 are withdrawn from consideration, claims 31 to 36 having been canceled.

Claims 1 - 18, 28 - 30, and 37 were examined. Claims 1-18, 28 -30, and 37 were rejected. No claims were allowed.

Claims 1, 11, 12, 14, 28, and 37 have been amended. Support for the amendments can be found in the claims as originally filed and throughout the specification at, for example: Claim 1: paragraphs [0065], [0069] and abstract, as well as figures and description thereof; Claim 12: page 27, paragraph [0111], and paragraph [0112], bridging pages 27 and 28; Claims 14 and 28: Amended for clarity; Claim 37: page 27, paragraph [0111], page 28, paragraph [0113]. In addition, newly added claims 38 to 44 find support in originally filed claims 19 to 26. As the above amendments introduce no new matter to the application, their entry is respectfully requested.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1 – 18, 28 – 30, and 37 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In view of the amendments to the claims and the remarks made herein, this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

Claims 1, 5, and 37 (Office Action, page 3)

The Office Action has rejected claims 1, 5, and 37, stating that the phrase “array of features” is vague and indefinite. The Office Action states that Page 9 of the specification defines the term “array”, but does not define the term “features”, and that it is unclear as to what an array of features refers to (Office Action, page 3). With respect

to this contention, Applicants respectfully disagree. Page 9, paragraph 36 of the specification states:

“An array includes any two dimensional or substantially two dimensional arrangement of spatially addressable regions (i.e. “features”) containing capture agents...”

Moreover, the specification at page 11, Paragraph 41 states the following:

“...An array is ‘addressable’ when it has multiple regions of different moieties (e.g., different capture agent) such that a region (i.e., a “feature” or “spot” of the array) at a particular predetermined location (i.e., an “address”) on the array will detect a particular sequence”.

A “feature” is clearly defined as a spatially addressable region on the array containing capture agents. An array is further defined as being addressable when it contains multiple regions of different capture agents such that each different region on the array detects a particular sequence. The specification clearly defines the term “features”, and makes it clear that an “array of features” refers to an array with different regions containing particular capture agents. Thus Applicants respectfully request that this rejection be withdrawn.

Claim 1 (Office Action, page 3)

The Office Action has rejected claim 1, stating that the term “processing” on line 4 is vague and indefinite. The Office Action states that the specification fails to define the term and that it is unclear as to what type of processing is involved (Office Action, page 3). With respect to this contention, Applicants respectfully disagree. Page 19, paragraph 76 states:

“In any of these embodiments, the subject analytes are usually processed for MALDI, i.e. ‘prepared for MALDI analysis’ prior to transfer to the sample plate, using ‘MALDI processing reagents’. MALDI processing reagents include cleavage reagents, derivatization reagents, and matrix.”

The subject analytes mentioned above are those from the sample that have been bound by capture agents on the array. The specification clearly defines the “processing” term as preparing the analytes for MALDI analysis prior to transfer to the MALDI sample plate, using MALDI processing reagents. In addition to listing some of the processing agents used in Paragraph 76 on Page 19, Paragraphs 77, 78, and 79 on Pages 19 and 20 elaborate on what this type of processing entails. The specification clearly defines the term “processing” and makes clear what is involved therein. Thus Applicants respectfully request that this rejection be withdrawn.

Claim 1 (Office Action, page 3)

The Office Action has rejected claim 1, stating that Step (b) of the claim is vague and indefinite. The Office Action states that it is unclear as to how the step of contacting a sample is related to the step of processing any analytes (Office Action, page 3). The amendment to claim 1 delineates that analytes of interest from the contacted sample are specifically bound by capture agents on the array with which it is contacted. Step (b) indicates processing of these analytes. In view of the amendments to the claims, specifically the amendment to claim 1, this objection may be withdrawn.

Claim 1 (Office Action, page 4)

The Office Action has rejected claim 1, stating that the term “features” on line 5 is vague and indefinite. The Office Action states that the specification does not define the term and that it is unclear as to what the term refers (Office Action, page 4). With respect to this contention, the Applicants respectfully disagree. Page 12, Paragraph 45 states:

“... a MALDI sample plate may contain a plurality of features, i.e. discrete, addressable regions, each containing a different analyte for ionization by the laser of the MALDI mass spectrometer.”

In addition, Page 17, Paragraph 66 states:

“In general, the MALDI sample plates, as employed in the subject methods, contain a plurality of fluid retaining structures. The areas on the surface of the MALDI sample plate defined by those structures are termed ‘features’ herein”.

The term “features” as it pertains to the MALDI sample plate is clearly defined in the specifications, and it is clear as to what the term refers to. Thus Applicants respectfully request that this rejection be withdrawn.

Claim 11 (Office Action, page 4)

The Office Action has rejected claim 11, stating that the term “affinity label” is vague and indefinite. The Office Action states that it is unclear what type of material the affinity label is and how it provides binding of the capture agents to the solid support as claimed (Office Action, page 4). The claim has been amended to clarify the claim to read “agent” in place of “affinity label”. Page 17, Paragraph 63 states:

“Attachment of a capture agent to a solid support may be facilitated by using a solid support that is coated with an agent that binds to the capture agent. For example, a solid support may be coated with an antibody – binding agent such as protein A or Protein G, or any other agent, e.g., streptavidin, avidin, glutathione, maltose, etc., that

can bind a suitable capture agent, e.g., a biotinylated capture agent or a capture agent containing a GST, Hist – tag or MPB moiety.”

The specification provides examples of the type of material comprising the agent used to facilitate binding of the capture agent and the solid support, as well as how this binding is achieved. In view of the amendment to the claim, the objection may be withdrawn.

Claim 28 (Office Action, page 4)

The Office Action has rejected claim 28, stating that the phrase “a method of claim 12” is vague and indefinite. The Office Action states that it is unclear as to which method the phrase refers (Office Action, page 4). The claim has been amended to read “A method comprising transmitting data from the method of claim 12...” clarifying that the whole method of claim 12 is the specific method to which the phrase refers. Therefore, this rejection may be withdrawn.

Claim 37 (Office Action, page 4)

The Office Action has rejected claim 37, stating that the term “process” on line 5 is vague and indefinite. The Office Action states that the specification fails to define the term and that it is unclear as to what type of processing is involved (Office Action, page 4). With respect to this contention, Applicants respectfully disagree. Page 19, paragraph 76 states:

“In any of these embodiments, the subject analytes are usually processed for MALDI, i.e. ‘prepared for MALDI analysis’ prior to transfer to the sample plate, using ‘MALDI processing reagents’. MALDI processing reagents include cleavage reagents, derivatization reagents, and matrix.”

The subject analytes mentioned above are those from the sample that have been bound by capture agents on the array. The specification clearly defines the “processing” term as preparing the analytes for MALDI analysis prior to transfer to the MALDI sample plate, using MALDI processing reagents. In addition to listing some of

the processing agents used in Paragraph 76 on Page 19, Paragraphs 77, 78, and 79 on Pages 19 and 20 elaborate on what this type of processing entails. The specification clearly defines the term “processing” and makes clear what is involved therein. Thus Applicants respectfully request that this rejection be withdrawn.

Claim 1 (Office Action, page 4, 5)

Claim 1 was rejected for lack of antecedent basis with respect to the limitation “any products from step (b)” in line 5. The claim has been amended to recite, “processed analytes” in place of “products”. Therefore, this rejection may be withdrawn.

Claim 14 (Office Action, page 5)

Claim 14 was rejected for insufficient antecedent basis for the limitation “said obtained molecular weights” in lines 1 – 2. The claim has been amended to recite, “... said determined molecular weights...” instead of “... said obtained molecular weights...” Therefore, this rejection may be withdrawn.

Claim 28 (Office Action, page 5)

Claim 28 was rejected based on insufficient antecedent basis for the limitation “data from a method of claim 12” in line 1. In view of the amendments to the claims, specifically the amendment to claim 12, this objection may be withdrawn.

Rejection under 35 U.S.C. §102

Little et al. (U.S. Pat. No. 6,387,628) (Office Action, page 5)

Claims 1 - 7, 10 – 15, 17, 18 and 37 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Little et al. (U.S. Pat. No. 6,387,628). In view of the amendments to the claims and the remarks made herein this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

The present invention is directed to a method for preparing a MALDI sample plate for MALDI mass spectrometry. As claimed, the methods require the use of a first array of array capture agents and a MALDI sample plate.

The array of capture agents as used in the claimed methods is one that is a planar substrate having a plurality of features on a surface thereof, where each feature includes a capture agent that specifically binds to an analyte and each feature is surrounded by a fluid retaining structure. An representative example of such an array is a multiwell plate where each well includes an antibody that specifically binds to a protein.

The MALDI sample plate that is employed in the subject methods is one that, like the capture agent array, includes a plurality of features each surrounded by a fluid retaining structure, e.g., a multiwell plate.

It is well established that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987). See also, Scripps Clinic and Research Foundation v. Genentech, Inc., 18 USPQ 2d 1001 (Fed. Cir. 1991).

Upon review of cited Little reference, there is no teaching in Little to employ an array of capture agents and a MALDI sample plate as claimed. Specifically, there is no teaching in little to employ an array of capture agents in the form of a planar substrate having a plurality of features on a surface thereof, where each feature is surrounded by a fluid retaining structure. Likewise, Little fails to teach a MALDI sample plate as claimed.

Thus, the cited reference fails to disclose every element found in the claims of the present invention. As such, Claims 1 – 7, 10 – 15, 17, 18, and 37 are not anticipated under 35 U.S.C. § 102(b) by the cited reference. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §103

Little et al. in view of Marshall et al. (U.S. Pat. No. 5,236,826) (Office Action, page 9)

Claim 8 has been rejected under 35 U.S.C. §103 (a) as being unpatentable for allegedly being rendered obvious by Little et al., (U.S. Pat. No. 6,387,628) in view of Marshall et al. (U.S. Pat. No. 5,236,826). In view of the amendments to the claims and remarks made herein this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

The law is clear that to establish a prima facie case of obviousness, the prior art reference, or references when combined, must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974). As noted above, Little et al. fails to teach each and every limitation found in the claims of the present application. In particular, Little et al. fails to teach a method of contacting a sample with an array of features containing different capture agents that specifically bind to a set of predetermined analytes of interest.

Marshall et al. was cited solely for teaching of washing bound and unbound material components in order to reduce the amount of background noise present by unbound signal generating material remaining in the zone of measurement. Thus, the cited reference fails to make up the deficiency of Little et al., as reviewed above. Therefore, the references alone or in combination do not teach each and every element found in the claims.

As such, since the combination of the cited references fails to teach or suggest each and every limitation found in the claims of the present application, the cited references fail to render the claims of the present application obvious. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Little et al. in view of Krantz et al. (U.S. Pat. No. 5,840,733) (Office Action, page 10)

Claim 9 has been rejected under 35 U.S.C. §103 (a) as being unpatentable for allegedly being rendered obvious by Little et al., (U.S. Pat. No. 6,387,628) in view of Krantz et al. (U.S. Pat. No. 5,840,733). In view of the remarks made herein this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

Krantz et al. was cited solely for teaching that samples for MALDI – MS were mixed on an analysis plate with a matrix and then dried, in order to allow for crystallization and insertion into the instrument for laser ionization. Thus the cited reference fails to make up the deficiency of Little et al., as reviewed above. Therefore, the references alone or in combination do not teach each and every element found in the claims.

As such, since the combination of the cited references fail to teach each every limitation found in the claims of the present application, the cited references fail to render the claims of the present application obvious. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Little et al. in view of El Shami et al. (U.S. Pat. No. 6,525,187) (Office Action, page 11)

Claim 16 has been rejected under 35 U.S.C. §103 (a) as being unpatentable for allegedly being rendered obvious by Little et al., (U.S. Pat. No. 6,387,628) in view of El Shami et al. (U.S. Pat. No. 6,525,187). In view of the remarks made herein this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

El Shami et al. was cited solely for teaching determining a test amount of an analyte, in order to compare an amount of an analyte in a subject sample to that of a normal amount of analyte from a healthy individual, wherein the analyte is a protein and

is detected using MALDI mass spectrometry. Thus the cited reference fails to make up the deficiency of Little et al., as reviewed above. Therefore, the references alone or in combination do not teach each and every element found in the claims.

As such, since the combination of the cited references fail to teach each every limitation found in the claims of the present application, the cited references fail to render the claims of the present application obvious. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Little et al. in view of Sugiyama et al. (U.S. Pat. No. 6,828,421) (Office Action, page 12)

Claims 28 - 30 have been rejected under 35 U.S.C. §103 (a) as being unpatentable for allegedly being rendered obvious by Little et al., (U.S. Pat. No. 6,387,628) in view of Sugiyama et al. (U.S. Pat. No. 6,828,421). In view of the remarks made herein this rejection is respectfully traversed as applied and as it may be applied to the pending claims.

Sugiyama et al. was cited solely for teaching the step of transmitting data in the form of email or posted on a website, wherein the data includes molecular weight information, in order to communicate information to other researchers in a different country. Thus the cited reference fails to make up the deficiency of Little et al., as reviewed above. Therefore, the references alone or in combination do not teach each and every element found in the claims.

As such, since the combination of the cited references fail to teach each every limitation found in the claims of the present application, the cited references fail to render the claims of the present application obvious. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Finally, newly added claims 38 to 44 are even further distinguishable over the cited references, as none of the references teaches or suggests practicing a method using an automated system, as claimed in these claims.

Conclusion

The Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,

Date: 6.30.05

By: _____

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